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### (54) Powder inhaler

Pulverinhalator

Inhalateur à poudre

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(56) References cited:  
**EP-A- 0 424 790 EP-A- 0 448 204  
WO-A-92/00771 DE-A- 1 498 398  
DE-A- 3 243 731 FR-A- 2 516 387  
FR-A- 2 662 936 US-A- 4 635 829**

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**Description**Field of the Invention

**[0001]** This invention relates to an inhaler for delivering a dose of a medicament comprising a metering device as defined in the preamble of claim 1.

**[0002]** Such an inhaler is known from WO-A-92/00771.

Background to the Invention

**[0003]** It is often necessary to transfer an accurate volume of a substance from a storage chamber containing that substance to another location, but it is not always easy to effect the transfer accurately and efficiently. In particular, it is often desired to transfer a powdered medicament from a storage chamber to an inhalation passage in a dry powder inhaler.

**[0004]** Powder inhalers, which deliver a drug in a dry, finely divided form, have been shown to give certain medical advantages over other forms of delivery system. In particular, they are more popular than inhalers which propel a drug in pressurised gas from an aerosol, because of environmental and other considerations.

**[0005]** EP-079478, EP-166294 and GB-2165159 disclose examples of dry powder inhalers which include a medicament storage chamber and an inhalation passage through which air is drawn via a mouthpiece. A metering member provided with a metering recess takes a dose of medicament from the storage chamber and deposits it in the inhalation passage.

**[0006]** It is considered that the accuracy of such arrangements can be very poor: on the one hand, by repeated indexing of the metering member it is possible to deposit two or more doses of medicament into the inhalation passage, resulting in the administration to the user of an overdose of medicament; on the other hand, since the medicament normally drops from the metering recess into the inhalation passage under gravity, particles of medicament can adhere to the interior of the metering recess so that an underdose is delivered.

**[0007]** US-2587215 discloses dry powder inhalers with the same disadvantages as those mentioned above. However, this document also discloses an embodiment in which the metering member presents the medicament in an upwardly open dispensing cup to a mixing chamber, where it is mixed with air before being sucked into an inhalation tube via a nozzle having a narrow opening. Air sucked into the inhaler passes into the inhalation tube either directly or through the mixing chamber and nozzle. Accordingly, not all the air passes over the dispensing cup. If medicament adheres to the surface of the dispensing cup but is not sucked therefrom, an underdose of medicament will be delivered to the user. Upon repeated use of a dispensing cup to deliver doses to the inhalation tube, a continually increasing amount of the medicament powder can adhere to

the base of the dispensing cup, resulting in progressively decreased dosages to the user.

**[0008]** This build-up of adherent powder is thought to be a source of inaccurate dosing in many of the inhalers previously proposed.

Moreover, in the inhaler of US-2587215, the metering member is a rotary sliding device journalised on a cylindrical pivot member extending from the bottom of the body of the device. Such an arrangement is susceptible to jamming due to ingress of powdered medicament between the cylindrical contacting surfaces of the pivot member and the metering member.

**[0009]** Another form of inhaler which is currently available includes a metering member having a number of

15 tapered metering recesses which are open at top and bottom. In use, finely divided medicament from a storage chamber is packed into the recesses, whereupon the metering member is moved to a dispensing position in which air can be drawn through the recesses to draw

20 out the medicament. This device is considered to have a number of major shortcomings. Firstly, the metering recesses are prone to clogging. Secondly, a large amount of suction is required, so that the device is unsuitable for use by patients with breathing problems.

25 Thirdly, two hands are required to operate the device.

**[0010]** An improvement over the above described inhalers is described in our earlier PCT patent application, No. WO-A-02/00771 (PCT/GB91/01147). This discloses an inhaler in which the metering member comprises 30 at least one dispensing cup which, when filled from a storage chamber with a dose of the substance to be delivered, is presented to the inhalation passage in an upwardly open position. The substance to be delivered is removed from the dispensing cup, rather than by the action of gravity, by air flow through the inhalation passage. Thus, in normal use of the inhaler, repeated indexing of the metering member should not result in multiple doses of the substance being delivered into the inhalation passage.

**[0011]** The inhaler described in WO-A-92/00771 (PCT/GB91/01147) incorporates means for ensuring that the dispensing cup is substantially free from the substance to be delivered, before it is presented to the storage chamber to be re-filled with the substance. This

45 means may comprise a specially shaped inhalation passage; means for moving the dispensing cup into a downwardly open position after it has been presented to the inhalation passage and before it is re-presented to the storage chamber; or means, such as resilient wiping

50 means, for dislodging any remaining substance from the cup after it has been presented to the inhalation passage. In all cases, at least one of these special means must be included in the inhaler so as to prevent any of the substance from remaining in the dispensing cup after it has been presented to the inhalation passage. If any of the substance did remain, this could affect accuracy when the dispensing cup was re-filled from the storage chamber ready for subsequent re-presentation to

the inhalation passage.

[0012] German Patent Application No. 3 243 731 describes a metering pen for delivering metered amounts of powder comprises a barrel having a delivery opening, and movably arranged therein a delivery or driving rod.

[0013] At the region adjoining the lower end portion of the rod forming a closure small piston, the rod is provided with an annular groove which can be brought, by displacing the rod downward to an opening and delivery position, in such a way that a metered amount of the substance to be supplied may exit the delivery opening.

[0014] US Patent No. 4,635,829 describes dispensing apparatus for dispensing discrete measured amounts of fluent material comprising a dispenser body which includes a horizontal tubular chamber having an upper inlet port and a lower outlet port in communication with the tubular chamber. A reservoir communicates with the inlet port. A piston having a plurality of vertical and horizontal measuring holes is disposed within the horizontal tubular chamber and configured for rotational and reciprocal linear sliding engagement with the tubular chamber and each of the measuring holes can alternatively communicate with the inlet port and the outlet port when so aligned.

[0015] The need to ensure that a metering member is substantially free from the substance to be delivered, after each presentation to the inhalation passage of an inhaler, arises largely from the fact that the metering chamber is constantly being re-presented to the storage chamber, re-filled with the substance and returned to the inhalation passage. The metering member is required to deliver an accurate dose of the substance each time it passes through the inhalation passage.

[0016] It is an aim of the present invention to provide improved means for accurately transferring a dose of a substance, such as a powdered drug, from one location to another, which means may be used, *inter alia*, in an inhaler to transfer a dose of drug from a storage chamber to an inhalation passage. An inhaler incorporating such means should overcome or at least mitigate the above described problems associated with conventional inhalers, and should be capable of delivering an accurate dose of drug to a user each time it is used.

#### Statements of the Invention

[0017] According to a first aspect of the present invention there is provided an inhaler for delivering a substance in a finely divided form as defined in claim 1.

[0018] Preferred embodiments are defined in the dependent claims.

[0019] The flowable substance may be a pulverulent material, for example a powdered drug.

[0020] Such a device allows the relatively simple and efficient transfer of precise volumetric doses of a substance from one location to another. Movement of the device from the storage chamber, through the outlet conduit, to another location causes the device to carry

with it as it moves a precisely defined dose of substance, trapped between the inner walls of the conduit. When the device exits the outlet conduit, the substance can then be released ready for use as desire.

5 [0021] According to a preferred embodiment of the present invention, there is provided an inhaler for delivering a substance in a finely divided form, the inhaler comprising a container.

[0022] The metering device may comprise a body in 10 the form of a spool which may be located in, and preferably pass through, the outlet conduit in use. The device may also be one of a plurality of such devices arranged in series, which devices are able to pass through the storage chamber and into the outlet conduit in series 15 so as to transfer a succession of metered doses of substance out of the storage chamber. In this case, the first end element of one device in the series may also serve as the second end element of the preceding device in the series, such that the desired volume is defined between two successive end elements as successive devices in the series pass into the outlet conduit in use.

[0023] According to a preferred embodiment of the invention a plurality of metering devices are arranged in series. The devices may be releasably or permanently 20 attached to one another so as to be in a chain-like conformation, preferably a flexible or semi-flexible chain. Such a design of metering devices such flexibility possible.

[0024] A series of metering devices is ideal for use in 25 an inhaler, because it allows sequential presentation of doses of a substance to the inhalation passage of the inhaler as the series is indexed through the inhaler. If the series is in the form of a flexible chain, it can then be rolled or folded up for compact storage in the inhaler.

30 The series may be of any appropriate length. It may, for instance, be supplied in a length greater than might be needed for use in an inhaler, but capable of being broken up into usable lengths.

[0025] A preferred inhaler thus preferably comprises 35 a plurality of metering devices arranged in a series, the series being movable as a series through the inhaler by means of the indexing means such that each metering device in the series may be moved via the outlet conduit from a first position, in which it is presented to the storage chamber to receive the substance, to a second position in which a desired volumetric dose of the substance has been transferred with that device to the inhalation passage.

[0026] So long as there is a sufficient number of metering devices in the series, a large number of doses can 40 be delivered to the user without any particular metering device necessarily being re-presented to the storage chamber after it has reached the inhalation passage. A flexible chain is able to comprise a large number of devices without assuming undue amounts of space in an inhaler. The preferred indexing means of an inhaler is 45 thus preferably operable to move the metering device, or each device in a series included in the inhaler, away

from the inhalation passage after it has reached its second position, in such a manner that the metering device is not re-presented to the storage chamber after having reached its second position.

[0027] In use of such an inhaler, the metering device moves, via the outlet conduit, from the storage chamber to the inhalation passage, where it delivers a volumetric dose of the substance, and thence to waste. It is not subsequently re-presented to the storage chamber to be filled with a further dose of the substance.

[0028] Since the metering device is not re-used, i.e. not used to deliver more than one dose of the substance to the inhalation passage, there is no need to incorporate in the inhaler means for ensuring that the metering device is substantially free from the substance after its presentation to the inhalation passage.

[0029] The inhaler preferably additionally comprises a waste chamber, in which the metering device may be housed after having been moved, by the indexing means, away from the inhalation passage.

[0030] Where the inhaler comprises a plurality of metering devices arranged in a series, operation of the indexing means preferably moves the series forward through the inhaler by the length of a fixed number of (typically one) metering devices, or of intervals between successive devices in the series, for each operation. Each metering device would thus pass in turn from its first to its second position, i.e. from the storage chamber to the inhalation passage, and preferably subsequently away from the inhalation passage and to a waste chamber. On passing from its first to its second position via the outlet conduit, each device would transfer to the inhalation passage a dose of substance, trapped between its first and second end elements and the inner walls of the outlet conduit as the device passes through the conduit.

[0031] The inhaler preferably comprises a number of metering devices which is either equal to or greater than the number of volumetric doses, of the substance to be delivered, which the storage chamber of the inhaler is adapted to hold. Thus, a large number of consecutive doses of the substance can be delivered to a user, even if the metering devices are not re-cycled inside the inhaler.

[0032] The metering devices in the series may be of such sizes and shapes as to allow delivery of different sized doses of the substance as the series is moved through the inhaler. For example, doses could be increased or decreased in volume over the length of the series, or otherwise varied in accordance with a course of treatment desired to be delivered by means of the inhaler.

[0033] Preferably, only one metering device of the series is presented to the inhalation passage at a time. Preferably, each time the indexing means is operated by a user, the metering device which has last transferred a dose of the substance to the inhalation passage is moved forward and replaced in the passage by the next

metering device in the series. Thus, the metering devices are used one after another, and preferably not re-used after presentation to the inhalation passage.

5 [0034] Where the inhaler comprises a series of metering devices, these are preferably arranged together in the form of a flexible or semi-flexible chain. This chain may then be wound around itself inside the inhaler, allowing a relatively large number of metering devices to be stored inside the inhaler. The inhaler preferably comprises a metering device housing, in which the or each metering device may be housed prior to being presented to the storage chamber. A series of metering devices may be stored in the housing, used devices then conveniently being housed in a waste chamber in the inhaler.

10 [0035] Alternatively, the metering devices may be housed in the storage chamber itself, prior to their being moved via the outlet conduit to the inhalation passage.

15 [0036] The inhaler may comprise more than one series of metering devices, which series are moveable through the inhaler in parallel with one another. The indexing means of the inhaler would conveniently be operable to move a metering device in one series from its first to its second position, and at the same time a metering device in another series from its first to its second position, such that both metering devices are presented simultaneously to the inhalation passage. This inhaler may comprise more than one storage chamber to correspond to the respective more than one series of metering devices, such that each series delivers, in use, a different substance to the inhalation passage. Such an arrangement might be of use, for instance, in delivering two drugs which are to be administered together but which should be stored separately prior to administration.

20 25 [0037] Alternatively, one of the series might be used to deliver a placebo and another a drug, relative amounts of the drug and placebo delivered being varied as the series are moved through the inhaler in use.

30 [0038] The metering devices are preferably joined together in the series, either permanently or releasably. They are preferably spaced at equal intervals along the length of the series, so as to transfer repeated doses of the same volume, although the devices may be spaced at intervals if it is desired to vary the volume of substance

35 40 to be transferred by each device. In particular, however, the series is preferably continuous, in the sense that as the series passes through the outlet conduit, the only substance transferred with it is that trapped between the end elements of each successive device, there being no spaces between an end element of one device and the next end element of the next device in the series.

45 [0039] Each metering device of the series must have at least a first end element, the simplest form being a disc or flange having the same cross-sectional size and

50 55 shape as that of the outlet conduit. Doses of the substance to be delivered are thus carried between the end elements of adjacent devices in the series. However, the metering devices may comprise bodies of any desired

size and shape, so as to define an appropriate dosage volume between two successive metering devices passing through the outlet conduit of the storage chamber. Effectively, the end elements act as "spacers" to define dose volumes as the series passes through the outlet conduit.

[0039] The shape of each metering device is preferably also such that, when air is drawn through the inhalation passage past a metering device present in the passage, substantially no part of the region of the metering device between its first and second end elements, which region defines the dose of the substance to be delivered, is sheltered from the air flow.

[0040] Thus, in the region of each device between end elements, as large a proportion as possible of the outer walls of the device should be parallel to the direction of air flow through the inhalation passage, when the metering device is presented to the inhalation passage in use.

[0041] The or each metering device may be disposable after it has been moved away from the inhalation passage. Alternatively, once all the metering devices of a series of devices have been passed through the inhaler, the series may be removed, as a chain, cleaned and inserted back into the metering device housing. The storage chamber of the inhaler would then be re-loaded with a fresh supply of the substance to be delivered, and the inhaler operated in the usual way to achieve movement of the cleaned metering devices through the inhaler, via the storage chamber and outlet conduit to the inhalation passage.

[0042] Where the inhaler comprises a series of metering devices arranged in a chain-like conformation, it may also comprise cutting means by which individual metering devices, or groups of metering devices, may be severed from the series after passing through the outlet conduit. The individual devices or groups of devices are more easy to house in the inhaler after use. The cutting means may comprise any appropriate arrangement, eg, a cutting blade and anvil, preferably linked to the indexing means so as to sever a metering device of the series after that metering device has passed through the outlet conduit.

[0043] The inhalation passage of the inhaler is preferably so shaped that a dose of the substance to be delivered, transferred to the inhalation passage by means of the metering device, is subjected to substantially the entire air flow through the inhalation passage when air is drawn in via the air intake means. In this way, whether air is drawn into the inhaler through a single opening or several openings, the air flow through the inhaler is such that all of the air flows along a single duct at the point where the metering device is presented to the inhalation passage. This helps to ensure that the entire dose of the substance is removed from the metering device when a user inhales via the air intake means.

The air intake means may comprise, for instance, a mouthpiece, so that a user may suck air into the inhaler

using his mouth. Alternatively, it may comprise a fitting capable of being inserted into the nostril, allowing a user to inhale from the inhaler through his nose. A baffle, of an appropriate size and shape, may be included within the mouthpiece or other fitting. This, together with the contours of the inhalation passage itself, assists in breaking up the substance to be delivered and mixing it with air flowing through the passage.

[0044] The indexing means of the inhaler may comprise a ratchet-like mechanism, which allows the passage of metering devices in a series through the outlet conduit and into the inhalation passage, say, one at a time. This will then allow each metering device a "stepped" movement, rather than continuous movement, from its first to its second position and subsequently away from the inhalation passage.

[0045] For instance, the indexing means may comprise first engaging means for engaging a first metering device in the series and conveying it to its next position; and biasing means for subsequently urging the first engaging means back into engagement with a second metering device in the series, thus releasing the first device for subsequent passage through the inhaler. A second engaging means preferably engages the series of metering devices following release of the first metering device by the first engaging means, so that the series is fixed in position whilst the first engaging means moves back into engagement with the second metering device. The engaging means will need to be appropriately shaped to interact with the metering devices, preferably in such a way that substance is not released from a metering device, during its movement through the inhaler, until that device is in a position to present its dose of substance to the inhalation passage.

[0046] The indexing means is preferably operable by pushing down a single button or handle on the inhaler to cause appropriate movement of the indexing means. For instance, such a button or handle might be connected to a piston moveable within the inhaler, which piston comprises at least the first engaging means of the indexing means. Preferably, the indexing means is linked to the operation of any cutting means in the inhaler, so that a single action by the user causes drug delivery, indexing and severance of the next used metering device.

[0047] In use, the storage chamber of the inhaler is preferably positioned above the inhalation passage, which in turn is positioned above any waste chamber included in the inhaler. The metering device is thus moved downwardly through the inhaler in normal use, and the substance to be delivered flows downwardly with it through the outlet conduit.

[0048] The inhaler may comprise a body made up of two separate components, the body defining the storage chamber, inhalation passage, air intake means and, where applicable, the waste chamber and the metering device housing. The two components of the body are conveniently arranged one at least partly inside the oth-

er and capable of a degree of telescopic movement relative to one another, with the inhaler comprising biasing means to urge the two components in a direction away from one another.

**[0049]** The internal construction of these body components, and the arrangement of the metering device(s) inside them, is preferably such that movement of the two components in a direction towards one another, against the action of the biasing means, releases the metering device(s) for movement from one position to the next. In this way, movement of the two components relative to one another constitutes operation of the indexing means of the inhaler. The biasing means (which may take the form of, for instance, a spring) will then urge the two components of the inhaler body away from one another again, to a "rest" position in which the metering device which has last been presented to the inhalation passage is "captured" in its second position until the next operation of the indexing means.

**[0050]** Preferably, one of the body components defines the storage chamber (and preferably also the metering device housing), the other a waste chamber. The inhalation passage is preferably defined inside that component which also defines the storage chamber.

**[0051]** Preferably, the inhaler may also include a moisture-absorbent material stored inside the storage chamber, together with the substance to be delivered, to ensure that the substance remains dry at all times.

**[0052]** The inhaler preferably includes display means, operable by the indexing means so as to display an item of information to a user. The display means may, for instance, comprise counter means for indicating to the user the number of times that a dose of the substance has been presented to the inhalation passage, and/or the number of metering devices still remaining to be so presented. Display means of this general type are already known for use in conventional inhalers.

**[0053]** The inhaler may additionally comprise a timer (eg, an electronic or mechanical timer) and associated control means for ensuring that the substance may only be transferred to the inhalation passage at a desired dosage rate and that the user is unable to inhale the substance more often than is medically desirable over a given time period. The control means may comprise locking means, by which the indexing means is prevented from further operation until a predetermined period of time has elapsed since its last operation.

**[0054]** A method of operating the inhaler may comprising the step of passing a metering device from the storage chamber into the outlet conduit so as to cause substance surrounding the device in the storage chamber to pass with the device into the conduit, in the space defined between the end elements of the device and the intervening section of the inner walls of the conduit, the shape and dimensions of the device relative to those of the outlet conduit being as described.

**[0055]** Such a method may involve the use of an inhaler in which case the method may be used to transfer

the substance from the storage chamber into the inhalation passage of the inhaler, via the outlet conduit.

**[0056]** A metering device may in particular be used to transfer a desired volumetric dose of a substance from a supply to a receptacle in which that dose is to be stored, for instance for subsequent use. The receptacle may be part of, for instance, a container for carrying one or more doses of a medicament for subsequent administration to a patient. The receptacle or container may be for use in an inhaler.

**[0057]** Thus, a method for use in loading a receptacle with a desired volumetric dose of a flowable substance, may comprising the steps of providing a storage chamber containing the substance and an associated outlet

15 conduit communicating with the chamber, and passing from the storage chamber into the outlet conduit a metering device, the shape and dimensions of the device relative to those of the outlet conduit being as described. In this way, substance enclosed between the first and second end elements of the metering device and the intervening section of the inner walls of the conduit, may be transferred to the receptacle when the metering device is passed into the receptacle from the outlet conduit.

**[0058]** Preferably, the receptacle is itself of such shape and dimensions (ie, typically in the form of a conduit passing through a body) that the metering device may pass into the receptacle and be located therein with its first and second end elements in sealing engagement

30 with the inner walls of the receptacle. A dose of substance may then be enclosed in the receptacle, trapped by means of the metering device. The relative dimensions of the metering device and receptacle are preferably such that the device, once located in the receptacle, 35 has a tendency to remain therein unless actively urged out of it. Thus, the receptacle and metering device together provide a sealed enclosure in which a metered dose of substance is or may be contained until such time as the device is urged fully or partially out of the receptacle (eg, pushed out) by appropriate means.

**[0059]** According to another preferred embodiment of the present invention, there is provided a receptacle in combination with a metering device located therein, as described above, the space defined by the device and 45 the inner walls of the receptacle having been loaded with a desired volumetric dose of a flowable substance. The combination may be used to store and transport the dose of substance prior to its use.

**[0060]** The receptacle may form part of a container 50 including a plurality of such receptacles, in each of which a desired dose of a desired substance may be held. Preferably, each receptacle in the container includes a metering device located inside the receptacle and is loaded with the desired flowable substance. The container may be adapted for use, for instance, in an inhaler, each dose of substance contained in its receptacles being presented to the inhalation passage of the inhaler at an appropriate point during use. Thus, the container

may be in the form of a drug-carrying "magazine" or cartridge.

**[0061]** According to a further preferred embodiment, the invention may provide a container including a plurality of receptacle-metering device combinations as described above.

**[0062]** Another method preferably involves passing through the storage chamber a plurality of metering devices, each device transferring as it is passed from the chamber into the outlet conduit its own metered dose of substance. Preferably, each device is passed to a separate respective receptacle, for instance in a container comprising several receptacles, so as to load each of the receptacles in turn with a desired dose of the substance.

**[0063]** Thus, such a method may comprise the steps of moving into position adjacent the outlet conduit a first receptacle in a series of receptacles; transferring a dose of the substance to the first receptacle by passing a first metering device from the storage chamber into the first receptacle; replacing the first receptacle with a second receptacle in the series of receptacles; and transferring a dose of the substance to the second receptacle by passing a second metering device (for instance, in a series of such devices) from the storage chamber into the second receptacle. These steps may be repeated as often as desired.

**[0064]** Preferably, each metering device of a series of devices passed through the storage chamber is separated from the next device in the series after the former has been passed out of the storage chamber. The product of such a method is a receptacle containing a single metering device and a dose of substance transferred with that device the combination of receptacle and device being in accordance with preferred embodiments of the invention.

**[0065]** The inhaler preferably comprises a plurality of such pre-loaded receptacle-metering device combinations, the receptacles forming part of a larger container. The container may comprise, for instance, a cartridge (conveniently circular) adapted for rotation inside the inhaler, by the indexing means, so that each receptacle may be positioned in turn in or adjacent the inhalation passage. Alternatively, the container may be in the form of a chain of receptacles arranged together in a series and adapted for linear movement through the inhaler.

**[0066]** The means for urging the metering device out of the receptacle may comprise, for instance, a plunger operable in association with the indexing means to push the metering device out of the receptacle.

**[0067]** Preferred embodiments of the present invention will now be described, by way of example only, with reference to the accompanying illustrative drawings, of which:-

Figures 1 and 2 show perspective views of drug-carrying containers;

Figure 3 shows longitudinal cross-sections taken through an inhaler incorporating the container shown in Figure 2; and

5 Figure 4 is an exploded perspective view of the inhaler of Figure 3.

#### Detailed Description of the Drawings

10 **[0068]** The invention is described firstly by reference to an inhaler which incorporates metering devices.

**[0069]** Figures 1 and 2 are perspective views of drug-carrying containers in accordance with a preferred embodiment of the invention. Each container comprises a 15 plurality of receptacles, in each of which receptacles a desired volumetric dose of a substance, in this case a drug, is held. The two containers are for use in an inhaler as defined in claim 1.

**[0070]** The container 120 shown in Figure 1 is in the 20 form of a "bandolier" made up of a series of units 121. Each unit, or receptacle, 121 is in the form of a cuboid body having an open-ended cylindrical conduit 122 running through it. A metering device 123, in the form of a spool, is located inside each conduit 122. Each spool 123 has upper and lower flanges 124 and a narrower neck portion 125. The flanges (end elements) 124 are a tight but slideable fit inside the conduit 122 and the overall length of the spool 123 is more or less the same as the overall length of the conduit 122.

**[0071]** When the bandolier 120 is ready for use in an inhaler, each conduit 122 contains one spool such as 123, and is filled with a powdered drug which occupies the space defined between the flanges 124, the neck portion 125 and the inner walls of the conduit 122. The 35 spool 123 and the conduit 122 are of such dimensions that this space is of the precise volume of the dose of drug to be delivered in use. Because the flanges 124 are a tight fit inside conduit 122, they provide seals at the open ends of the conduit, to prevent escape of the drug contained in it. The spools may, however, be pushed out of either of the open ends of the conduits by suitable means provided in the inhaler, at the time when the dose of drug contained in the conduit is to be delivered to the user.

**[0072]** The container 128 shown in Figure 2 is in the 40 form of a disc which carries around its periphery a series of conduits 129 similar to conduits 122 shown in Figure 1. When the container is ready for use, each conduit 129 contains a metering device of similar form to spool 123

50 shown in Figure 1, with a desired quantity of drug trapped between the outer flanges of the metering device and the inner walls of the conduit 129. Each of the conduits in the container thus contains one dose of the drug, each to be delivered to a user in turn when the container is used in an inhaler. The doses may be of the same or differing amounts in the conduits of the container; if they are of differing amounts, this may be achieved by using metering devices of differing shapes and sizes.

[0073] Figure 3, parts A-C shows an inhaler in accordance with a preferred embodiment of the present invention, in various stages of its use. The exact construction of most parts of the inhaler 140 is not critical to the invention, although it can be seen that it comprises a cover 141 which is removed prior to use (Figures 3B and C) and a mouthpiece 142 through which the user may suck air which enters the inhaler as shown at 143 and passes through the inhalation passage 144.

The inhaler 140 contains a disc-like magazine 145, similar to the container shown in Figure 2 and having a plurality of drug-carrying receptacles around its periphery. Suitable indexing means, including a push button 146 and a ratchet mechanism 147, engages with the upper surface of disc 145. As shown in Figure 3B, depression of the push button 146 (as shown by the arrow) pushes spool 148 downwards and almost fully out of a first receptacle, positioned adjacent the inhalation passage 144, into the inhalation passage (Figure 3B). As the spool 148 is pushed into the inhalation passage, it carries with it the measured quantity of drug which it has been used to contain inside the magazine 145. The user can then inhale through the mouthpiece 142 so as to take up the drug now released into the inhalation passage. The upper flange of the spool remains, however, held by the lower part of the receptacle.

[0074] When the user then releases push button 146, the ratchet mechanism 147 causes disc 145 to rotate by one step so that the next receptacle is brought into register with the inhalation passage 144. The inhaler is thus reset and ready for delivery of another dose of drug. The "empty" spool 148, not having been pushed fully out of the first receptacle, continues to move round with the first receptacle, supported by the lower guide 150.

[0075] In an inhaler such as that shown in Figure 3, the metering devices may alternatively be pushed upwardly towards an inhalation passage positioned above the drug-filled receptacles in use.

[0076] Figure 4 shows an exploded perspective view of the components of the inhaler 140 shown in Figure 19. It can be seen that the upper surface of disc 145 is specially profiled so as to engage with the ratchet mechanism 147 provided on the underside of push button 146. The inhaler is also provided with conventional display means (now shown) for displaying to the user, through window 149, an indication of the number of doses already taken or alternatively of the number of doses remaining in magazine 145.

[0077] It will be understood that an inhaler such as that shown in Figures 3 and 4 is a preferred embodiment. Other examples, comprising different types of drug container, different ways of mounting the container, different types of indexing means, etc are also possible. The container may, for instance, take the form of a chain of receptacles such as the bandolier 120 shown in Figure 1. Each receptacle in the container may carry more than one metering device, if necessary to increase the capacity of the container overall. The inhaler may be

provided pre-loaded with a container carrying the required number of drug doses. The container may be removable and refillable or replaceable once empty.

[0078] The advantages of using a metering device in accordance with the present invention, particularly in a powder inhaler, are that the volume of substance transferred with each metering device can be accurately controlled. In a drug-carrying container in accordance with the invention, the type of substance carried may be different in each of its receptacles. In a preferred inhaler, the use of a metering device ensures that the accurately defined dose of drug carried with the metering device is entirely transferred to the inhalation passage and may then be subjected to substantially all the air flow, thus reducing the risk of the user receiving an incorrect dosage.

## Claims

1. An inhaler for delivering a substance in a finely divided form, the inhaler comprising air intake means (142) by which air may be drawn into the inhaler from the atmosphere and an inhalation passage (144) communicating with the air intake means, through which passage (144) air may be drawn using the air intake means (142) and indexing means (146,147) operable to move a receptacle (121) into a position in or adjacent the inhalation passage (144); **characterised in that** the receptacle (121) has a conduit (122) into which a metering device (123;148) is located, and the metering device (123; 148) has a narrow neck portion (125), located between the first and second sealing elements (124), which defines the dosing space against the conduit (122) of the receptacle (121) loaded with a desired volumetric dose of the substance, the relative dimensions of the metering device (148) and receptacle (121) being such that the device has a tendency to remain in the receptacle (121) unless actively urged out of it; and means for urging the metering device (148) at least partially out of the receptacle (121) so as to release the dose of substance contained in the receptacle (121) into the inhalation passage (144) when the receptacle occupies its position in or adjacent the inhalation passage.
2. An inhaler according to Claim 1 in which a plurality of such receptacle-metering device combinations are provided in the form of a container (145).
3. An inhaler according to Claim 2 in which the container (145) is adapted for rotation inside the inhaler, by the indexing means (146,147) so that each receptacle (121) may be positioned in turn in or adjacent the inhalation passage (144).
4. An inhaler according to Claim 2 in which the con-

tainer comprises a chain of receptacles (120) arranged together in a series and adapted for linear movement through the inhaler by the indexing means.

5. An inhaler according to any one of Claims 1 to 4, in which the means for urging the metering device out of the receptacle comprises a plunger operable in association with the indexing means (146,147) to push the metering device (148) out of the receptacle (121).

6. An inhaler according to any one of Claims 1 to 5, in which the metering device (148) comprises a body in the form of a spool and the first and second end elements comprise flanges (124) at respective ends of the body which are a tight slidable fit inside the receptacle (121).

#### Patentansprüche

1. Inhalator zum Abgeben einer Substanz in fein verteilter Form, wobei der Inhalator Mittel (142) für den Lufteinlass umfasst, durch welche Luft von der Atmosphäre in den Inhalator gezogen werden kann, und eine mit den Mitteln für den Lufteinlass in Verbindung stehende Inhalationspassage (144), wobei Luft durch die Passage (144) unter Verwendung der Mittel (142) für den Lufteinlass und von Mitteln zur Anzeige (146, 147) gezogen werden kann, wobei diese zum Bewegen einer Aufnahme (121) in eine Position in oder angrenzend an die Inhalationspassage (144) betätigbar ist;  
**dadurch gekennzeichnet, dass** die Aufnahme (121) einen Kanal (122) aufweist, in dem eine Messeinrichtung (123; 148) angeordnet ist, wobei die Messeinrichtung (123; 148) einen schmalen Halsabschnitt (125) besitzt, welcher zwischen dem ersten und den zweiten Dichtungselementen (124) angeordnet ist, wobei der Halsabschnitt den Dosis-Raum gegenüber dem mit der gewünschten Volumendosis der Substanz beladenen Kanal (122) der Aufnahme (121) definiert, wobei die relativen Dimensionen der Messeinrichtung (148) und der Aufnahme (121) so sind, dass die Einrichtung eine Tendenz zum Verbleib in der Aufnahme (121) besitzt, bis sie aktiv aus dieser hinaus gedrängt wird; und durch Mittel zum wenigstens teilweise Herausdrängen der Messeinrichtung (148) aus der Aufnahme (121) zum Abgeben der in der Aufnahme (121) enthaltenen Dosis der Substanz in die Inhalationspassage (144), wenn die Aufnahme ihre Position in oder benachbart zur Inhalationspassage einnimmt.

2. Inhalator nach Anspruch 1, in dem eine Vielzahl derartiger Aufnahme-Messeinrichtung-Kombinationen in der Form eines Containers (145) vorgese-

hen sind.

3. Inhalator nach Anspruch 2, in dem der Container (145) zur Rotation in dem Inhalator mittels der Anzeigeeinrichtungen (146, 147) eingerichtet ist, so dass jede Aufnahme (121) wiederum in der oder angrenzend an die Inhalationspassage (144) positioniert werden kann.

5. Inhalator nach Anspruch 2, in dem der Container eine Kette von in einer Reihe angeordneten und für eine lineare Bewegung durch den Inhalator mittels der Anzeigeeinrichtungen eingerichteten Aufnahmen (120) umfasst.

10. Inhalator nach Anspruch 2, in dem die Einrichtungen zum Herausdrängen der Messeinrichtung aus der Aufnahme einen in Verbindung mit den Anzeigeeinrichtungen (146, 147) betätigbaren Stempel zum Herausdrücken der Messeinrichtung (148) aus der Aufnahme (121) umfasst.

15. Inhalator nach einem der Ansprüche 1 bis 4, in dem die Einrichtungen zum Herausdrängen der Messeinrichtung aus der Aufnahme einen in Verbindung mit den Anzeigeeinrichtungen (146, 147) betätigbaren Stempel zum Herausdrücken der Messeinrichtung (148) aus der Aufnahme (121) umfasst.

20. Inhalator nach einem der Ansprüche 1 bis 5, in dem die Messeinrichtung (148) einen Körper in der Form einer Spule umfasst und die ersten und zweiten End-Elemente Kragen (124) an den jeweiligen Enden des Körpers umfassen, die eng gleitbar in das Innere der Aufnahme (121) passen.

25. Inhalator nach einem der Ansprüche 1 bis 5, in dem die Messeinrichtung (148) einen Körper in der Form einer Spule umfasst und die ersten und zweiten End-Elemente Kragen (124) an den jeweiligen Enden des Körpers umfassen, die eng gleitbar in das Innere der Aufnahme (121) passen.

30. Inhalator nach einem der Ansprüche 1 bis 5, in dem die Messeinrichtung (148) einen Körper in der Form einer Spule umfasst und die ersten und zweiten End-Elemente Kragen (124) an den jeweiligen Enden des Körpers umfassen, die eng gleitbar in das Innere der Aufnahme (121) passen.

35. Inhalator pour la distribution d'une substance sous une forme finement divisée, l'inhaleur comprenant des moyens d'admission d'air (142) par lesquels l'air peut être extrait de l'atmosphère vers l'inhaleur et un passage d'inhalation (144) communiquant avec les moyens d'admission d'air, passage (144) à travers lequel l'air peut être extrait en utilisant les moyens d'admission d'air (142) et des moyens d'indexation (146, 147) aptes à déplacer un réceptacle (121) dans une position dans le, ou adjacente, au passage d'inhalation (144); **caractérisé en ce que** le réceptacle (121) a un conduit (122) dans lequel un dispositif de mesure (123 ; 148) est disposé, et le dispositif de mesure (123 ; 148) a une partie en col étroit (125), disposée entre les premier et second éléments de joint (124), qui définissent l'espace de dosage contre le conduit (122) du réceptacle (121) chargé avec une dose volumétrique désirée de la substance, les dimensions relatives du dispositif de mesure (148) et du réceptacle (121) étant telles que le dispositif a une tendance à rester dans le réceptacle (121) à moins qu'il soit poussé activement hors de celui-ci; et des moyens pour pousser le dispositif de mesure (148) au moins partiellement hors du réceptacle (121) de manière à libérer la do-

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se de substance contenue dans le réceptacle (121) dans le passage d'inhalation (144) quand le réceptacle occupe sa position dans ou adjacente au passage d'inhalation.

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2. Inhaleur selon la revendication 1, dans lequel une pluralité de telles combinaisons de dispositifs de mesure - réceptacle sont prévus sous la forme d'un conteneur (145).

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3. Inhaleur selon la revendication 2, dans lequel le conteneur (145) est adapté pour la rotation dans l'inhaleur, par les moyens d'indexation (146, 147) de manière à ce que chaque réceptacle (121) soit positionné respectivement dans le, ou de manière 15 adjacente au, passage d'inhalation (144).

4. Inhaleur selon la revendication 2, dans lequel le conteneur comprend une chaîne de réceptacles (120) arrangée ensemble en série et adaptée pour un mouvement linéaire à travers l'inhaleur par les moyens d'indexation. 20

5. Inhaleur selon l'une des revendications 1 à 4, dans lequel les moyens pour pousser le dispositif de mesure hors du réceptacle comprennent un piston fonctionnel en association avec les moyens d'indexation (146, 147) pour pousser le dispositif de mesure (148) hors du réceptacle (121). 25

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6. Inhaleur selon l'une des revendications 1 à 5, dans lequel le dispositif de mesure (148) comprend un corps sous la forme d'une cuillère et les premier et second éléments d'extrémité comprennent des rebords (124) aux extrémités respectives du corps qui sont un ajustement étroit coulissable dans le réceptacle (121). 35

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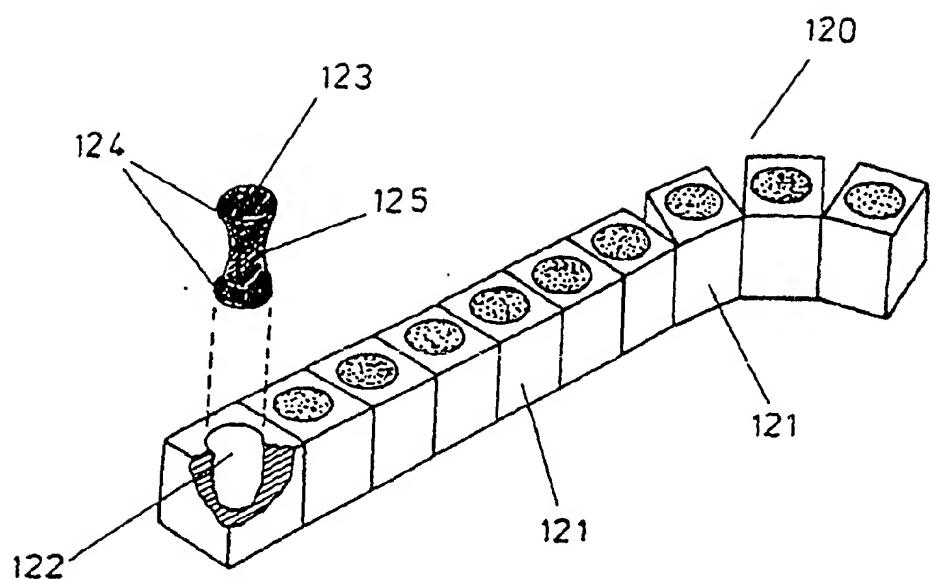


FIG. 1

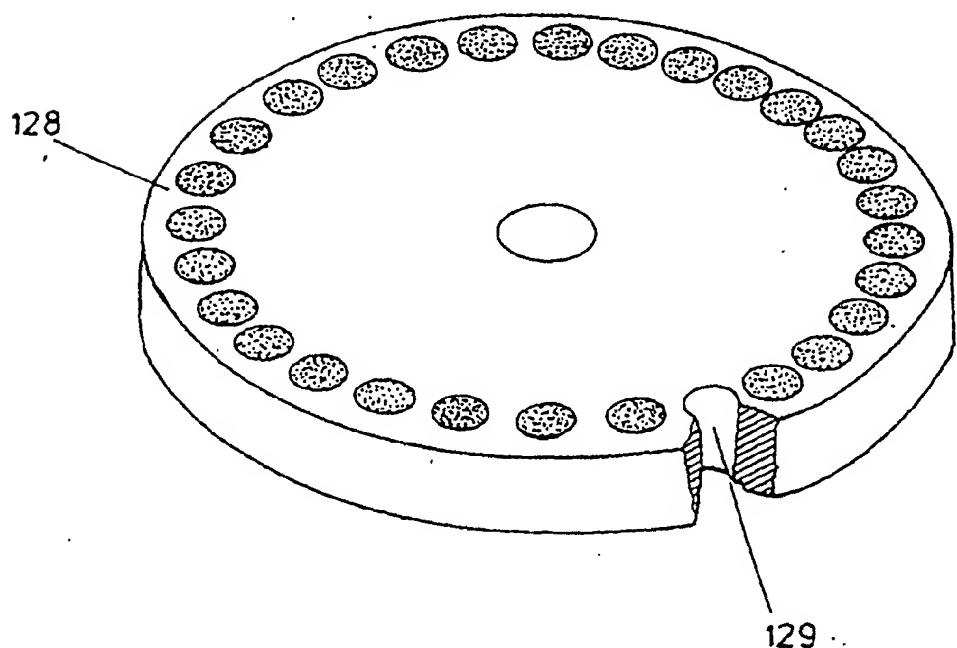


FIG. 2

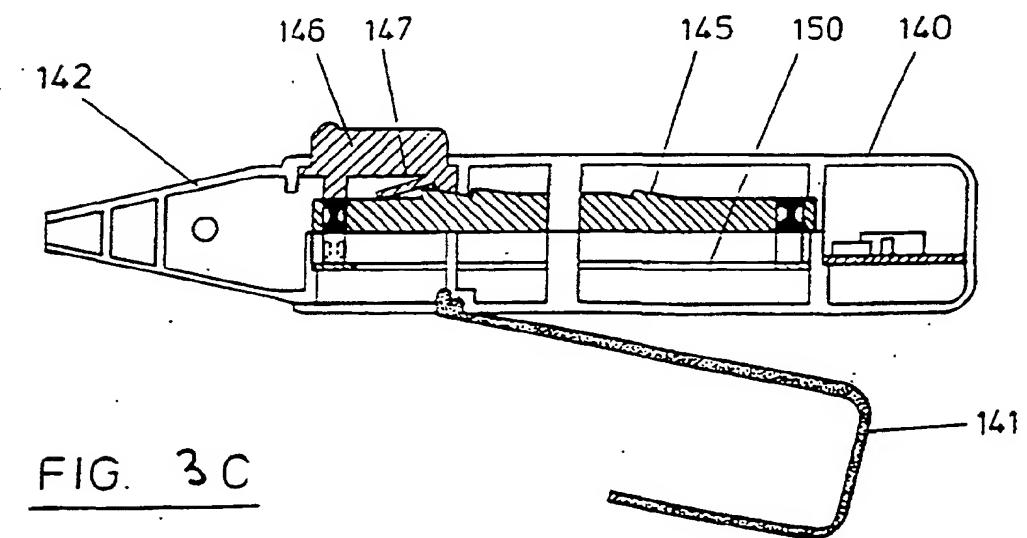
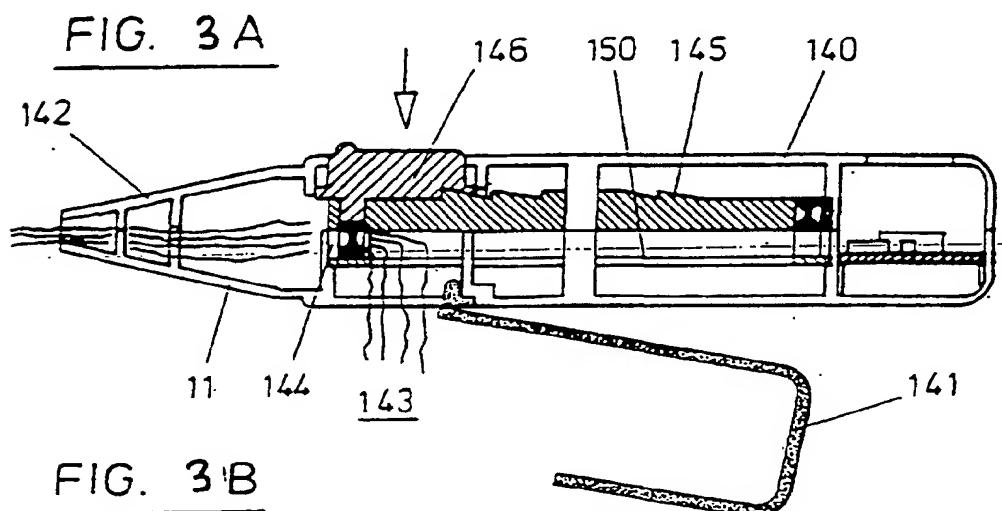
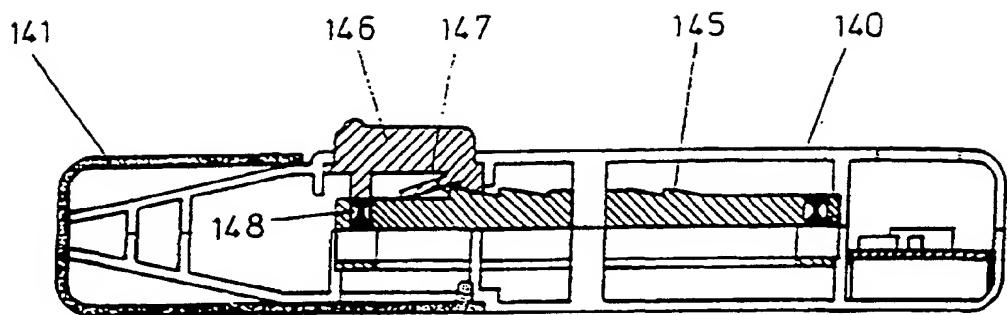


FIG. 3

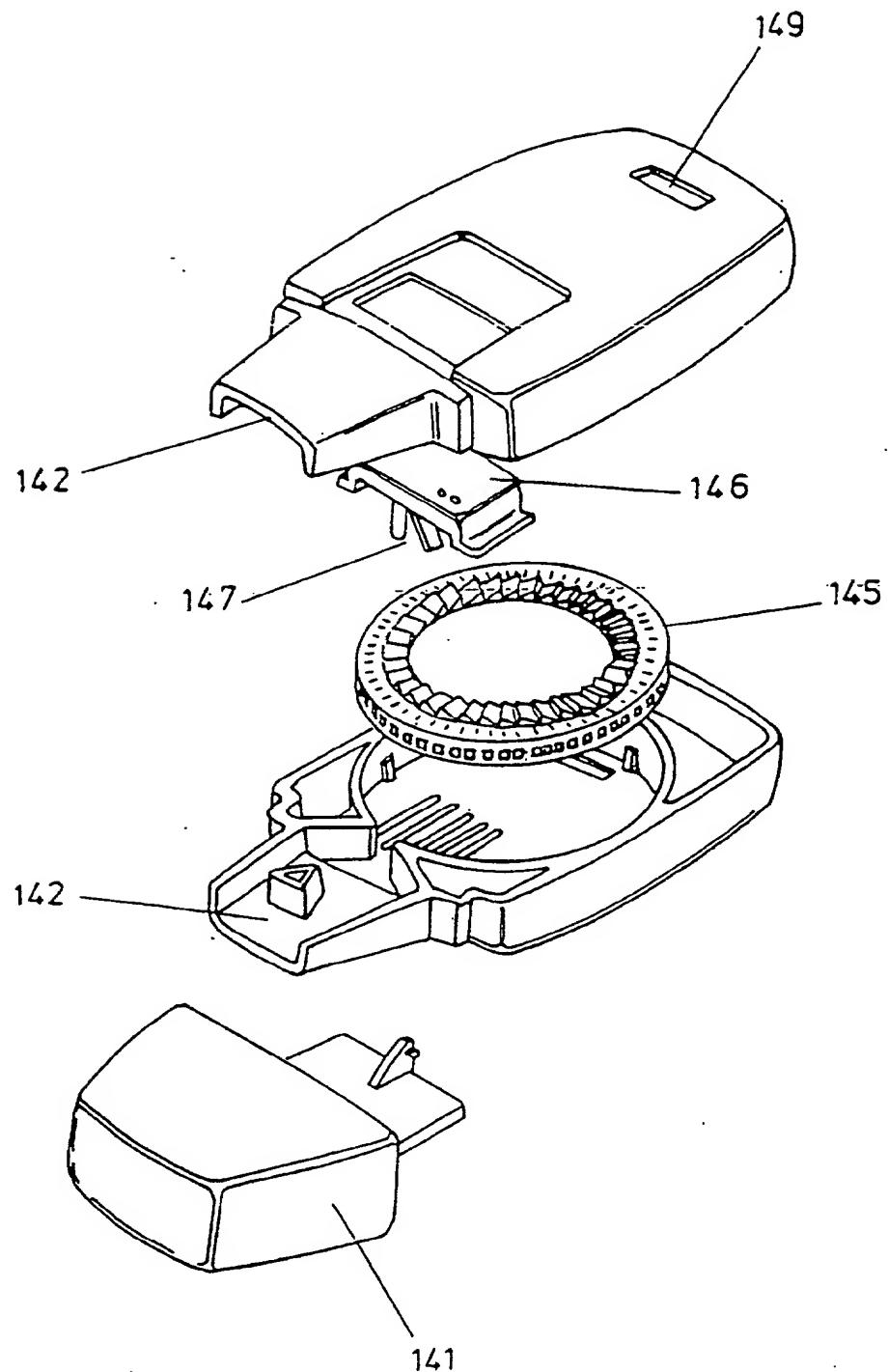


FIG. 4